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Palliative care in patients with ovarian cancer and bowel obstruction.

[Daniele A](#)¹, [Ferrero A](#), [Fuso L](#), [Mineccia M](#), [Porcellana V](#), [Vassallo D](#), [Biglia N](#), [Menato G](#).

1 **Palliative care in patients with ovarian cancer and bowel obstruction**

2 **A. Daniele^a, A. Ferrero^a, L. Fuso^a, M. Mineccia^b, V. Porcellana^c, D. Vassallo^d,**
3 **N. Biglia^a, G. Menato^a**

4 ^a Academic Division of Gynecology and Obstetrics - Mauriziano Hospital, Via
5 Magellano,1 -10128 - Turin (Italy)

6 ^b Department of Surgery - Mauriziano Hospital, Via Magellano,1 -10128 - Turin
7 (Italy)

8 ^c Service of Palliative care - Mauriziano Hospital, Via Magellano,1 -10128 - Turin
9 (Italy)

10 ^d Service of Dietetics - Mauriziano Hospital, Via Magellano,1 -10128 - Turin (Italy)

11

12 **Corrisponding author:**

13 Alberto Daniele

14 Address: Ospedale Mauriziano, Via Magellano, 1 -10128- Torino (Italy)

15 Phone: +39-011.5082682

16 Mobile : +39.3489324133

17 Fax: +39.011.5082683

18 E-mail: albertodaniele@hotmail.

19

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ABSTRACT

Objective: Bowel obstruction (MBO) is usually a pre-terminal event in patients with ovarian cancer. However, because of the lack of data in literature, decisions around surgical intervention, non resectional procedures or medical treatment of MBO in patients with ovarian cancer can not be lightly undertaken. We analyzed medical and surgical procedures, performance status, nutritional status, cachexia and their prognostic value in this group of patients.

Methods: We retrospectively selected all consecutive patients with recurrent ovarian cancer who received medical or surgical treatment for MBO between October 2008 and January 2014 at the Academic Department of Gynecological Oncology of Mauriziano Hospital of Turin (Italy).

Results: We found 40 patients: 18 of them underwent medical treatment and 22 of them were submitted to surgery. In the group of surgery, the hospitalization was shorter (p: 0.02), the pain reduction was more effective (p: 0.001), the number of chemotherapy lines was higher (p: 0.03) and re-obstruction was more rare (p: 0.02). Between the two groups, we did not find any differences in post-palliation episodes of vomit (p: 0.83), type of diet (p: 0.34), ability to return home (p: 0.72) and death setting (p: 0.28). Median survival after palliation was longer in the group of surgery (p: 0.025). Cachexia, low performance status and poor nutritional status were significant predictors of worse survival after MBO, independently by the treatment.

Conclusions: Surgery has to be considered in patients without serious contraindications, otherwise a medical protocol, including antisecretory drugs, is the standard of care in frail patients.

INTRODUCTION

Bowel obstruction is defined as the situation in which the normal intestinal transit is abnormally delayed or completely stopped. It is a common complication in patients with end-stage cancer and it is estimated that malignant bowel obstruction (MBO) involves 3% of the patients admitted in Hospice. The reported frequency varies from 25% to 50% in patients with advanced ovarian cancer [1]. Survival is generally poor, with a reported median survival of 1-3 months, but some studies have demonstrated survival of up to 1 year.

In the patients with advanced ovarian cancer, more often the intestinal occlusion is due to the diffuse peritoneal carcinomatosis. MBO may be sometimes the consequence of the cancer treatment: adhesions from previous surgery, radiation enteritis, chronic ischemia, neurotoxicity from Vinca Alkaloids or narcotic intestinal syndrome from the use of opioids.

Bowel obstruction can be partial or complete and can occur at single or multiple sites. Small bowel obstruction is more common than large bowel obstruction (61 vs 33%) and both sites are involved in > 20% of patients [2].

Therapy directed at MBO must achieve certain goals, such as allowing the patient to return home, restoration of oral intake and relief of abdominal distension and pain. Once the obstruction is relieved, a small proportion of patients is suitable for further treatment with chemotherapy.

Although bowel obstruction in advanced ovarian cancer presents quite commonly, its management still remains a challenge, mainly because it has been the focus of very few clinical trials. Because of the lack of the evidences in literature, decisions around surgical intervention, non resectional procedures or medical treatment of malignant intestinal obstruction cannot be lightly undertaken. The survival benefit from the

70 different strategies is difficult to validate because of the heterogeneity of the
71 populations studied in various trials, particularly with respect to the primary cancer
72 type. Studies so far have measured perioperative mortality and morbidity but have
73 not taken the quality of life (QOL) into account when measuring the success of any
74 procedures [3].

75 The aim of the study was to compare the two different strategies, medical and
76 surgical, in the management of MBO in ovarian cancer patients. We evaluated if
77 operative and conservative approaches produce an effective and durable palliation in
78 terms of QOL and survival. Furthermore, we investigated the prevalence of low
79 performance status, poor nutritional status and cachexia in ovarian cancer patients
80 with MBO and whether the results correlated with overall survival.

81

82 MATERIAL AND METHODS

83 All consecutive patients with recurrent ovarian cancer who experienced bowel
84 obstruction between October 2008 and January 2014 at the Academic Department of
85 Gynecological Oncology of Mauriziano Hospital of Turin (Italy) were identified
86 through the discharging program of the Division. We excluded patients with MBO
87 for other gynecological malignancies, non-epithelial or borderline ovarian cancer,
88 patients with bowel obstruction for benign causes, patients with a history of previous
89 or concurrent malignancy and patients with concomitant recto-vaginal fistula.

90 The diagnosis of MBO was based on history, signs and symptoms, physical
91 examination and radiological findings. At the moment of hospital admission, all
92 patients underwent some laboratory tests and a chest-abdominal computed
93 tomography (CT) to identify the site of bowel occlusion and to restage the disease.

94 Because the location of the MBO can determine the treatment options, we
95 distinguished the site of obstruction in large, small and both small and large bowel.
96 The selected patients received medical or surgical treatment.

97 Medical management of the patients with MBO considered the following protocol:

- 98 - Morphine Sulphate 60 mg, Haloperidol 1.5 mg, Octreotide 0.3 mg [4]
99 through continuous subcutaneous pump infusion per day;
- 100 - Dexamethasone 8 mg intravenous per day;
- 101 - Stop oral intake;
- 102 - Parenteral liquids.

103 Surgical management consisted of the less invasive and most conservative
104 interventions to palliate symptoms and to restore intestinal function.

105 The significance of the palliative treatment was largely explained to the patients and
106 for the surgical procedures an informed consensus was signed by the patient and by
107 the surgeon. Patients and their families during the palliative care for the MBO were
108 followed by the team of gynecological oncology, a nutritionist, a palliative care
109 physician, a group of three colorectal surgeons and a nurse expert in ostomy
110 management. All patients were visited by all the specialists during the process of
111 care. At discharge, patients underwent chemotherapy, if indicated, or palliative care
112 at home or in hospice.

113 We collected the following data on the history of the patients relative to three stages:

- 114 I- *Before MBO*: stage of the ovarian cancer at diagnosis (FIGO), date of the end
115 of the primary treatment, date of the recurrence, platinum sensitivity, number of
116 chemotherapy lines, secondary surgery and radiotherapy;
- 117 II- *Time of MBO*: performance status (Karnofsky scale), nutritional status (PG-
118 SGA) [5-6], cachexia (CCSG) [7], body mass index (BMI - kg/m²), comorbidities,

119 date of MBO, vomit, pain (NRS), palpable abdominal mass, CT scan findings
120 (peritoneal carcinomatosis, abdominal or extra-abdominal disease, ascites > 2 L and
121 the site of obstruction), serum sodium (mEq/L) serum kalium (mEq/l), calcium
122 (mg/dl), serum creatinin (mg/dl), total serum protein (g/dl), serum albumin (mg/dl),
123 haemoglobin (g/dl), C-reactive protein (mg/l), medical or surgical management, type
124 of surgical procedure, surgical morbidity and mortality, duration of the
125 hospitalization (days);

126 III- *After MBO*: pain (NRS), vomit, type of diet at discharge (oral, oral and
127 parenteral or parenteral), ability to return home, accesses to emergency department
128 and re-hospitalization for re-obstruction and successive medical or surgical
129 intervention, number of chemotherapy lines, death setting (hospital, hospice or
130 home) and survival.

131 The range from the end of the primary treatment and the diagnosis of relapsed cancer
132 was defined disease free interval (DFI) and the recurrent disease was considered
133 platinum sensitive when it reappeared after a DFI > 6 months.

134 The study was approved by the Local Ethics Committee.

135

136 *Statistical analysis*

137 Differences in the groups were analyzed using the Student's t-test for continuous
138 variables or the U Mann-Whitney Test when a normal distribution was not assumed
139 (Non parametric test); the Pearson chi-square test was adopted to compare
140 frequencies. Overall survival curves were plotted according to the Kaplan–Meier
141 product limit method and analyzed by the Log-Rank test. Multivariate analysis was
142 performed using the Cox's proportional hazards logistic regression. Alfa level of less
143 than or equal to 0.05 were considered statistically significant.

RESULTS

Patients characteristics

Between October 2008 and January 2014, 53 patients were hospitalized in our division with the admission diagnosis of intestinal occlusion. Thirteen patients with MBO for endometrial, non-epithelial or borderline ovarian cancer, 5 patients with bowel obstruction for benign causes, 2 patients with a history of previous or concurrent malignancy and 3 patients with concomitant recto-vaginal fistula were excluded. Data from the remaining 40 patients with concomitant recurrent epithelial ovarian cancer and malignant bowel obstruction were collected. At ovarian cancer diagnosis, 4 patients were stage I-II and 36 patients were stage III-IV, according to FIGO. All patients underwent debulking surgery and all patients, except one, received neoadjuvant or first-line platinum based chemotherapy. Median DFI was 10 months (range 3 - 96 months). In three cases, the diagnosis of recurrent disease was concomitant to MBO. Before MBO, the median number of chemotherapy line was 3 lines (range 1 - 7). One patient was submitted to radiotherapy for a muscle-skeletal recurrence of the ileo-psoas region and one patient received radical secondary cytoreductive surgery. The median interval from the diagnosis of ovarian cancer to MBO was 26 months (range 3–149 months). The median age at first episode of MBO was 63 years (range 24 – 79 years). Nineteen patients suffered from at least one comorbidity and the most frequent was hypertension. Eighteen patients underwent medical treatment and 22 patients were submitted to surgery. Data of the patients at the moment of hospital admission for MBO are summarized in Table 1. We found 4 clinical factors, amongst the 12 analyzed, who resulted significantly different between the two groups: performance and nutritional status, pain ($\text{NRS} \geq 7$) and ascites. Considering the laboratory tests, only the levels of serum albumin were

169 significantly higher in the group undergoing surgery (p: 0.01). At hospital admission,
170 after the radiological restaging (chest-abdomen CT), thirty-two patients were
171 classified stage FIGO III C (macroscopic peritoneal metastasis beyond the pelvis
172 more than 2 cm), three patients were classified FIGO IV A (pleural effusion) and five
173 patients were classified FIGO IV B (three patients with liver metastasis, one with
174 pulmonary hilum lymph nodes metastasis and one with muscle-skeletal metastasis).
175 On the basis of the FIGO staging, no difference has been found between the two
176 groups.

177 *Medical treatment*

178 The medical protocol controlled symptoms within 4 days (range 1 – 9 days) and the
179 median hospitalization duration was 8 days (range 3-25 days). No side effects were
180 reported. Data about diet, re-obstruction, vomit and chemotherapy after MBO are
181 reported in Table 2. Median survival after MBO for the group of medical treatment
182 was 5.7 months (range: < 1 - 8.4 months). At the moment, 17 patients died, 4
183 (22.2%) in hospital, 3 (16.7%) in hospice, 10 (55.5%) at home and 1 patient is still
184 alive with disease.

185

186 *Surgical treatment*

187 Surgical procedures included 4 (18.9%) bowel resection and anastomosis, 9 (40.9%)
188 bowel resection and ostomy (2 colostomy and 7 ileostomy), 8 (36.4%) exclusive
189 ostomy (1 colostomy and 7 ileostomy) and 1 (4.5%) positioning of colonic stent. One
190 patient (4.5%), who underwent large bowel resection and anastomosis, had a
191 postoperative recto-vaginal fistula and required a re-intervention and ileostomy. The
192 mortality within 30 days from surgery was 4.5% (1 case), who died from progression
193 of tumour. Five patients (22.7%) underwent surgery within 24 hours from the

194 hospital admission, but there were no more complications or longer hospitalization in
195 this group. Median hospitalization was 14 days (range 8 - 30 days). Data about diet,
196 re-obstruction, vomit and chemotherapy after MBO are reported in Table 2. The
197 median survival after MBO for the group of surgical treatment was 13.6 months
198 (10.1 – 17.0 months). Nineteen patients died of disease, 6 (27.3%) in hospital, 4
199 (18.9%) in hospice, 9 (40.9%) at home, and 3 (13.6%) patients are still alive with
200 disease.

201

202 *Comparison of treatments*

203 Median hospitalization was shorter for the medical than for the surgical treatment (p:
204 0.02). Pain reduction one week after palliation was significantly more effective in the
205 surgical group (p: 0.001). The number of accesses to emergency department and re-
206 hospitalization for re-obstruction was significantly higher in the group of medical
207 treatment and in these patients the medical protocol was applied or reapplied (p:
208 0.02) (Table 2). After intestinal occlusion, the number of chemotherapy lines was
209 higher in the surgical group (p: 0.03). Between the two groups we did not find any
210 difference in post-palliation episodes of vomit (p: 0.83), type of diet (p: 0.34), ability
211 to return home (p: 0.72) and death setting (p: 0.28). The median survival after
212 palliation was longer in the group of surgery (p: 0.025) (Fig. 1).

213 In the group of surgery, patients had a better performance and nutritional status, but
214 no differences were shown about cachexia (Table 1). Cachexia, defined by the CCSG
215 criteria, increased the risk of death with an odds ratio of 3.2 (95% C.I. 1.5-6.6) (p:
216 0.001), the performance status amplified the risk of death with an odds ratio of 2.3
217 (95% C.I. 1.4-3.7) (p: 0.0001) and having a poor nutritional status (SGA-C) enlarged

218 the risk of death with an odds ratio of 4.7 (95% C.I. 1.4-14.9) (p: 0.008), compared to
219 well nourished patients (SGA-A).

220 In the multivariate logistic regression analysis (Cox proportional hazard model),
221 including as co-variables all the considered variables, CCSG cachexia and
222 performance status resulted independent prognostic factors (p: 0.0001) (Table 3).

223

224 **DISCUSSION**

225

226 Bowel obstruction is usually a pre-terminal event in patients with ovarian cancer. For
227 this reason, the relief of symptoms is the first aim of the treatment of these patients,
228 but the clinical management is not completely defined. Many treatment options,
229 medical approaches, endoscopic procedures and surgical interventions have been
230 proposed, but current evidences do not provide a standard of care. Modern medical
231 protocols include the use of somatostatine analogs (Octreotide), that inhibits the
232 release of gastro-intestinal secretions and regularizes the intestinal motility [4].
233 Surgery remains a discussed issue in patients with advanced cancer.

234 In patients with MBO, the major perplexities concern the success of conservative
235 treatment and the safety of operative management. Tang et al. reported that only
236 3.8% of complete obstruction resolved with conservative management [8]. In a later
237 study, 43% of 329 patients were successfully treated conservatively but with a re-
238 obstruction rate of 40.5% [9]. On the other hand, palliative surgery was associated
239 with a reported morbidity of 5% – 49% and mortality of 5% – 15% [10-11-12].
240 Major operative complications are fistulas, anastomotic leaks and sepsis. In our
241 study, the post-operative morbidity and mortality were low (4.5% each). We
242 registered only 1 case of recto-vaginal fistula, who required a re-intervention and
243 ileostomy, and 1 case of death within 30 days from surgery due to tumour

244 progression. In similar recent studies, Kolomainen et al. found an operative mortality
245 and morbidity rate of 18% and 27%, respectively [13], and Perri et al. described a
246 mortality rate of 14.7% within 30 days[14]. Medina-Franco et al. described a hospital
247 mortality rate of 10.8% and a postoperative morbidity of 16.2%, and the factors
248 associated with a significant increase of surgical mortality were: advanced patient
249 age, hypoalbuminemia, ovarian neoplasms and poor performance status [14].

250 In patients with MBO and recurrent ovarian cancer, the reported median survival is
251 3–6 months after palliation [15-16]. More recent series reported a median survival of
252 11.4 – 12.6 months in patients undergoing surgery for MBO versus 3.7 – 3.9 months
253 for non-surgical patients [17]. In our study, the median survival after palliation was
254 13.6 months for the group of surgery and 5.7 months for the group of medical
255 treatment. Mangili et al. also found a longer survival in the surgical group [18] and
256 Kolomainen et al. reported a median overall survival after surgical management of
257 MBO around 3 months (range: 2 days – 6 years) [13]. Table 4 compares the reported
258 survival after palliation in the literature.

259 In the present study, amongst the analyzed factors, the two groups of treatment
260 showed 5 significant differences: performance status, nutritional status, pain, ascites
261 and albumin. There were not any differences between the two groups in terms of age,
262 FIGO stadiation, number of previous chemotherapy lines, DFI, time from ovarian
263 cancer diagnosis and MBO and time from the last chemotherapy infusion. In the
264 group of surgery, the number of chemotherapy lines after MBO was higher, 15
265 patients (68.2%) received at least one line and 5 patients (22.7%) completed more
266 than one line (p: 0.03).

267 In our series, many QOL criteria were considered in the analysis. Pain reduction was
268 more effective in the surgical group and re-obstruction was more frequent in the

group of medical treatment. Between the two groups we did not find any difference in post-palliation episodes of vomit, type of diet and ability to return home. As reported, 2 essential QOL factors, pain reduction and re-obstruction, were significantly improved by surgical palliation. In case of re-obstruction, all patients received medical treatment. Two reports, each describing a small series of ovarian cancer patients who underwent exploratory laparotomy for recurrent bowel obstruction, reported successful palliation in 30% of cases [2-3]. In accordance with the cited studies, because of the high morbidity rate, the rapid development of subsequent bowel obstructions and the limited survival, we agree that a non-surgical approach is probably preferable for patients who experience repeated bowel obstruction. Because of the retrospective design, we lack data from some overall QOL questionnaires [18-19].

Considering some selection bias, our data suggest that patients who underwent palliative surgery achieve more effective survival and QOL improvements, but because of the reported implications, the decision to proceed with surgical palliation in patients with ovarian cancer and MBO has to be carefully evaluated for each individual patient.

Several studies have focused their attention to the identification of some prognostic factors for the selection of patients who may benefit from surgery. Mangili et al. suggested that the surgical approach seems to be useful for patients with life expectancy greater than 2 months [20]. Studies identified age, ascites, previous radiotherapy, multiple bowel obstructions, carcinomatosis, palpable masses and short interval from diagnosis to obstruction as clinical indicators of poor prognosis after surgery [13-21-22-23-24]. Henry et al. proposed a nomogram of 4 identified risk factors: carcinomatosis on imaging, leukocytosis, normal albumin and non

gynecologic cancer, that revealed which patients with complete small bowel obstruction might benefit from surgery [25]. However, because only the 17% of the included patients had gynecologic malignancies, their findings might not be fully applicable to gynecological oncology. Finally, in the study of Perri et al., a 4-variable score was correlated with the 30 days and 60 days overall survival after surgical palliation for MBO in gynecologic malignancies: 2.7% and 5.4%, respectively (score 0-1), and 40% and 73.3%, respectively (score 3-5). The score includes age above 60, ascites of more than 2 L, non-ovarian primary tumor and albumin < 2.5 g/dl [3]. The first three factors were assigned a value of 1 if present and 0 if not. Albumin < 2.5 mg/dl was assigned a value of 2 if present and 0 if not. The proposed scoring system is easy to apply and might facilitate decision of the healthcare team and information of patients and families. The major limitation of this score is that it does not take into account information about performance status.

Different tools have been proposed for cancer malnutrition and wasting assessment. They have been largely confirmed in gastro-intestinal cancer patients, but they have never been validated in ovarian cancer neoplasm. We designed the second part of the study to identify the role of performance status, nutritional status and cachexia in ovarian cancer patients with MBO and their association with survival after palliation, independently by the treatment. Thirteen patients (32.5%) had a low performance status and, finally, in accordance with PG-SGA classification, 8 patients (20%) were “severely malnourished”. Figures 2-3-4 show that low performance status, CCSG cachexia and poor nutritional status were all significant predictors of worse survival after MBO. To the best of our knowledge, the present study is the first that applied these assessment tools in such homogeneous group of patients with advanced ovarian carcinoma. The CCSG definition of cachexia was first introduced in a study of

319 patients with pancreatic carcinoma in which cachexia was found to be related to the
320 patients' survival [26]. In that study, 60% of the patients had cachexia and the HR for
321 overall survival was 2.23, close to our findings. These observations suggest that the
322 CCSG definition of cachexia should be applicable also in advanced ovarian
323 carcinoma. In this study, CCSG cachexia and low performance reached statistical
324 significance in both unadjusted and adjusted survival analyses and were the most
325 powerful predictors of survival. The sample size of the study was limited, and further
326 investigations are required to confirm the prognostic value of the nutrition and
327 cachexia assessments.

328 In our report, especially for the group of surgery, the long prognosis, the low rates of
329 postoperative morbidity and mortality and the high number of patients who received
330 chemotherapy after MBO probably reflect the good performance status of the
331 patients. Furthermore, previous reports date back several decades and so they do not
332 take into account the substantial improvements of the current medical protocols,
333 surgical techniques and anaesthesia. On the basis of our experience, we support the
334 hypothesis that performance and nutritional status and cachexia may address the
335 choice of the treatment.

336 All series, including ours, are retrospective and include a small numbers of patients,
337 but our study solely comprised ovarian cancer patients treated in a relatively short
338 period. In the analysis, we focused specific attention to QOL outcomes. Moreover,
339 our results come from a single institution and patients were assessed by a
340 multidisciplinary team.

341 In the setting of palliative care, a randomized trial is challenging [27]. A trial
342 comparing therapies for MBO will help to define therapy and identify selection
343 criteria. Untill now, no comparative trials have been performed on the role of the

344 therapeutic strategies for MBO. To prove the effects of any given treatment,
345 hundreds of patients would need to be recruited. A trial in this scenery is hampered
346 by many individual differences between patients and by the myriad of advanced
347 medical and surgical protocols. Currently, in the absence of a shared protocol, it is
348 our intention to validate our findings in a prospective study.

349 In conclusion, malignant bowel obstruction represents a common end-of-life event in
350 ovarian cancer patients. Because of its complexity and frailty of involved patients, a
351 multidisciplinary and collaborative approach is mandatory for an optimal clinical
352 management and palliation of MBO. In a palliative setting, the most important goal
353 is to identify the patient's expectations, because they are largely subjective for each
354 individual patient [28]. For these reasons, patients, and eventually their families,
355 must be informed about their health and life expectancy. Surgery has to be
356 considered in patients without serious contraindications, otherwise a combination of
357 opioids, anti-emetics, corticosteroids and antisecretory drugs is the mainstay in
358 patients with poor general conditions.

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Conflict of interest

Authors have no financial and personal relationships with other people or organizations that could inappropriately influence this work.

We have full control of all primary data and we agree to allow the journal to review data if requested.

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